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**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/109,119 06/30/98 BOLDT

B GTIBEN, 001

EXAMINER

HM22/0531

EXAMINER D, J PAPER NUMBER

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DATE MAILED:

05/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.**Commissioner of Patents and Trademarks**

Office Action Summary	Application No.	Applicant(s)	
	09/109,119	BOLDT ET AL.	
	Examiner	Art Unit	
	Jeanine A Enewold	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on 07 March 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All
 - b) Some *
 - c) None of the CERTIFIED copies of the priority documents have been:
 1. received.
 2. received in Application No. (Series Code / Serial Number) _____.
 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed March 7, 2000. Currently, claims 1-20 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
2. Any objections and rejections not reiterated below are hereby withdrawn.
3. This action contains new grounds of rejection necessitated by amendment.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 8, 13, 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "substantially complementary" in claims 1, 13 and 17 is a relative term which renders the claim indefinite. The term "substantially complementary" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Response to Arguments

The response traverses the rejection. The response asserts that the term has been defined in the specification on page 12, line 28 to page 13, line 8. This argument has been reviewed but is not convincing because the passage cited in the response provides examples of what substantially complementary may mean, but does not provide an exact definition. While the claims are read in light of the specification, limitations of the specification are not read into the claims. Thus for the reasons above and those already of record, the rejection is maintained.

B) The term "diagnostic section" in claims 1, 13, and 17 is a relative term which renders the claim indefinite. The term "diagnostic section" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Using this term renders the target of the primer indefinite.

Response to Arguments

The response traverses the rejection. The response asserts that the term is clearly defined on page 11, lines 10-20 as a specific portion of the target molecule. This argument has been reviewed but is not convincing because while the term is defined as a genomic target sequence which contains at least one potential mismatch nucleotide, this encompasses all nucleic acid molecules since mutations may be present in nearly every sequence. Thus, a "diagnostic section" is not adequately defined by the specification". Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Harris et al (US Pat. 5,849,544).

Harris teaches a method by which a specific DNA which may have clinical significance is amplified and captured to a solid support and the said DNA is later detected (abstract, claim 15, col. 1, lines 40-56 and col. 24, lines 4-24). This method includes capturing the amplified polynucleotide strands to a probe and denaturing them (col. 1, lines 40-56, col. 3 and 4). The amplified polynucleotides are separated into single-stranded polynucleotides (col. 4, lines 25-27).

Harris also teaches the support can be a microtitre plate (col. 6, lines 22-33). They also teach using enzyme labels, fluorescent labels, biotin and streptavidin as reporter labels (claim 14, col. 5, line 37). Harris teaches that this process can be used to detect a point mutation (claim 15, col. 24, line 16) which is interpreted to be the same as a mismatch.

In addition Harris teaches the use of a kit for testing the DNA for inherited or not inherited conditions (col. 1, lines 58-67, col. 2, lines 7-17, col. 24, lines 4-50).

Response to Arguments

The response traverses the rejection. The response asserts "Harris performs amplification that is not dependent upon a base mismatch at or near the 3' end of their primer". Further the response asserts that the instant invention is based upon an efficient amplification if no mismatch is present and no or inefficient amplification if at least one mismatch is present. This argument has been reviewed but is not convincing because the limitation that a base mismatch is at or near the 3' end of the primer is not a limitation of the instant claims. The claim is drawn to adding a primer substantially complementary to a diagnostic section of the genomic DNA selected from a Markush group which includes a primer having no mismatch bases (step b). Furthermore, the other member of the Markush group only requires a mismatch, without mention as to where this mismatch is located. Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-16 are indefinite over the recitation "efficiently amplifying the diagnostic section" because "efficiently amplifying" is vague and indefinite. The metes and bounds of the term are unclear. It is unclear whether efficiently amplifying means amplifying all of the nucleic acid molecules present, amplifying a certain percentage or whether the term may encompass some other meaning. Thus, efficiently amplifying renders the claims indefinite.

Conclusion

- 7. No claims allowable over the art.**
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold
May 24, 2000

Lisa B. Arthur
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PRIMARY EXAMINER
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